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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,118	12/11/2003	Sarah S. Bacus	CST-213	4570

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EXAMINER	
UNGAR, SUSAN NMN	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 10/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/735,118	BACUS ET AL.	
	Examiner	Art Unit	
	Susan Ungar	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *one* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *21 July 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *84-110* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) *84-110* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Claims 84-110 are pending in the application and are currently under prosecution.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group A. Claims 84-88, 89-92 as drawn only to inventions claimed in claim 84, as well as claims 99-101 as drawn only to inventions claimed in claim 84, as well as claims 103, 105-107 as drawn only to inventions claimed in claim 84 are drawn to multiple methods using combinations of multiple agents drawn to identifying a HER-2 overexpressing mammalian tumor that is likely to respond to a HER-2 directed therapy comprising assaying a sample to detect the pattern of NDF and IGFR and optionally phosphorylated S6 ribosomal polypeptide, classified in Class 435, subclass 4, 6, 7.1. For each of the claimed inventions, Applicant is required to elect one of the following:

A. detect a pattern of expression of NDF and IGFR polypeptide by assaying protein as disclosed in the specification;

B. detect a pattern of expression of NDG and IGFR polypeptide by assaying with nucleic acid probe as disclosed in the specification;

C. detect a pattern of phosphorylation of NDG and IGFR polypeptide;

D. detect a pattern of phosphorylation of NDG, IGFR, S6 ribosomal polypeptide.

E. detect a combined pattern of polypeptide expression (either by assay of protein as disclosed in the specification or by assaying with nucleic acid probe) and phosphorylation, wherein it is required that the specific

combination of expression and phosphorylation as well as the method of assay must be specifically identified.

It is noted for Applicant's convenience that although claim 84 is apparently claimed in a Markush format and claim 89, is claimed in a Markush format, the claims are drawn to multiple methods using combinations of multiple agents which do not share, as a whole, a substantial structural feature disclosed as being essential to their utility. Thus, the analysis of the claims, for restriction purposes, is subject to the findings of the court wherein the court found that unity of invention exists where entities included within a Markush group share a substantial structural feature disclosed as being essential to utility of the Markush group, In re Harnisch, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Since the members of the groups do not share a substantial structural feature disclosed as being essential to utility of the Markush group, the groups as claimed fail the Harnisch test and the claims are not accorded Markush restriction practice because they do not meet the requirements to be accorded Markush practice under MPEE 803.02 and the inventions are distinct for the reasons set forth below. Given that the claims fail the Harnisch test, it is further noted for Applicant's convenience that this is **NOT** a requirement for the election of a species, but rather a requirement for the election of a specific GROUP for examination.

Group B. Claim 89, only as it is drawn to inventions other than inventions drawn solely to the detection of a pattern of expression and/or phosphorylation of IGFR polypeptide, NDF polypeptide phosphorylated S6 ribosomal polypeptide, 93-107 are drawn to multiple methods using combinations of multiple agents drawn to identifying a HER-2

overexpressing mammalian tumor that is likely to respond to a HER-2 directed therapy comprising assaying a sample to detect the pattern of NDF, IGFR, phosphorylated S6 ribosomal polypeptide, EGFR, phosphorylated AKT, phosphorylated ERK, classified in Class 435, subclass 4, 6, 7.1. For each of the claimed inventions, Applicant is required to elect one of the following:

A. detect a pattern of expression of specifically identified polypeptides by assaying protein as disclosed in the specification;

B. detect a pattern of expression of specifically identified polypeptides by assaying with nucleic acid probe as disclosed in the specification;

C. detect a pattern of phosphorylation of specifically identified polypeptides;

D. detect a combined pattern of specifically identified polypeptide expression (either by assay of protein as disclosed in the specification or by assaying with nucleic acid probe) and specifically identified phosphorylation, wherein it is required that the specific combination of expression and phosphorylation as well as the method of assay must be specifically identified.

Claims 93-107 will be examined only as they are drawn to the invention elected above.

It is noted for Applicant's convenience that claim 89, although claimed in Markush format, is drawn to multiple methods using combinations of multiple agents which do not share, as a whole, a substantial structural feature disclosed as being essential to their utility. Thus, the analysis of the claims, for restriction purposes, is subject to the findings of the court wherein the court found that unity of invention exists where entities included within a Markush group share a

substantial structural feature disclosed as being essential to utility of the Markush group, In re Harnisch, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Since the members of the groups do not share a substantial structural feature disclosed as being essential to utility of the Markush group, the groups as claimed fail the Harnisch test and the claims are not accorded Markush restriction practice because they do not meet the requirements to be accorded Markush practice under MPEE 803.02 and the inventions are distinct for the reasons set forth below. Given that the claims fail the Harnisch test, it is further noted for Applicant's convenience that this is **NOT** a requirement for the election of a species, but rather a requirement for the election of a specific GROUP for examination.

Group C. Claims 108-110 drawn to kits comprising antibodies classified in Class 530, subclasses 387.1, 389.1. It is noted for Applicant's convenience that claim 108 is drawn to 120 kits. For Applicant's convenience, it is noted that, given that all of the kits are required to comprise antibody to HER-2 as well as one or more of 6 additional antibodies the number of kits claimed is $2^N - (N+1)$ or 124-8=120. Further, it is noted for Applicant's convenience that claim 108, although claimed in Markush format, is drawn to kits with multiple combinations of antibodies which do not share, as a whole, a substantial structural feature disclosed as being essential to their utility. Thus, the analysis of the claims, for restriction purposes, is subject to the findings of the court wherein the court found that unity of invention exists where entities included within a Markush group share a substantial structural feature disclosed as being essential to utility of the Markush group, In re Harnisch, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Since the members of the

groups do not share a substantial structural feature disclosed as being essential to utility of the Markush group, the groups as claimed fail the Harnisch test and the claims are not accorded Markush restriction practice because they do not meet the requirements to be accorded Markush practice under MPEE 803.02 and the inventions are distinct for the reasons set forth below. Given that the claims fail the Harnisch test, it is further noted for Applicant's convenience that this is **NOT** a requirement for the election of a species, but rather a requirement for the election of a specific GROUP for examination. Applicant is required to elect and identify a kit with a specific combination of antibodies.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups A and B are materially distinct methods which differ at least in objectives, method steps, reagents, response variables, and criteria for success. For example, Each of the groups differ in the combinations of polypeptides to be assayed, each group differs in the combinations of whether or not expression of mRNA or protein is in fact assayed, each group differs in combinations of protein expression or phosphorylation. The number of groups to be assayed is very large. Searching all of the groups with all of the different objectives, reagents, method steps, response variables, and criteria for success would invoke a high burden search.

The invention of Group C are materially distinct products having different structural formulas wherein the antibodies bind to different epitopes on different antigens and therefore have different functions. Search for one antibody is different from the search for another antibody. Because the groups comprise numerous

antibodies with different structure and function, searching of any of the inventions of group C 1-9 together would invoke a serious search burden.

The inventions of Groups C and A/B are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP*. **806.05(h)**]. In the instant case the antibody products as claimed can be used in a materially different process such as production of anti-idiotypic antibodies against the claimed antibodies.

Further, each of Groups A-C are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the patentability of the combination does not rely necessarily and solely on the patentability of any one subcombination and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the patentability of the combination does not rely necessarily and solely on the patentability of any one subcombination as clearly evidenced by the plural subcombinations claimed. Further, each of the subcombinations has utility by itself because each of the subcombinations are useful for screening for different variables and different markers. Thus the claims are distinct as required by MPEP 806.05(c).

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

7. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or

allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

.9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at 571-272-0787. The fax phone number for this Art Unit is (571) 273-8300.

Susan Ungar, PhD
Primary Patent Examiner
September 25, 2006